12-18-06

Attorney Docket No. 57070-8021.US00

OVP Express Mail Label No. EV 326 984 628 US

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: YUAN et al.

**APPLICATION No.: 10/591,358** 

FILED: August 31, 2006

FOR: TRIPTOLIDE DERIVATIVES FOR

MDULATION OF APOPTOSIS AND

**IMMUNOSUPPRESSION** 

EXAMINER: To be Assigned

**ART UNIT: 1625** 

Conf. No: 9546

# Information Disclosure Statement Within Three Months of Application Filing or Before First Action – 37 C.F.R. § 1.97(b)

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## 1. Timing of Submission

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last (37 C.F.R. § 1.97(b)). The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

## 2. Cited Information

- Copies of references 1-8 are issued patent(s) and published application(s) and are not included (see C.F.R. § 1.98(a)(2)(i)).

# 3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior

art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

#### 4. <u>Fee Payment</u>

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2207.

### 5. Patent Term Adjustment (37 C.F.R. § 1.704(d))

The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted, Perkins Coie LLP

Date: December 14 2000

Brian S. Beyer/

Registration No. 52,643

#### **Correspondence Address:**

Customer No. 22918
Perkins Coie LLP
P.O. Box 2168
Menlo Park, California 94026
(650) 838-4300



# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Form PTO-1449 (Modified) (Use several sheets if necessary)

of

1

Sheet

2

COMPLETE IF KNO	NWO
Application Number	10/591,358
Filing Date	August 31, 2006
First Named Inventor	Yuan et al.
Group Art Unit	1625
Confirmation No.	9546
Examiner Name	To be Assigned
Attorney Docket No.	57070-8021.US00

L					L	Automey Bocket No					,
				U.S.	PATENT	DOCUMENTS					
Examiner Initials	Cite No.	U.S. Patent or Application  Kind Code  NUMBER (if known)			Name of Patentee or Inventor		Date of Publication or Filing Date of Cited Document		Pages, Columns, Lines, Where Relevant Figures Appear		
	1.	4,005		I I		Kupchan et al.		7/87		guics / tppcui	1
	2.	5,294	·		Lipsky et al.		3/94				1
	3.	<del></del>		Α	Qi et al.		9/97				1
	4.	5,962,516		Α	Qi et al.		10/99				1
	5.	5,972,998			Jung et al.		10/99				1
	6.	6,004,999		Α	Jung et al.		12/99				1
	7.	6,150,539 A		Α		Musser					]
	8.	6,569	,893	B2	Dai et a	ıl.	5/03			~~~	]
			1	FOREI	GN PATE	NT DOCUMENT	S				
Examiner Initial	Cite No.	Foreign Patent or Applic Office NUMBER		ication Kind Code		nt	Date of Publication Filing I of Cite	ion Date d	Pages, Columns, Lines, Where Relevant Figures Appear	Т	
- Index	9.	JP	03 178		0000	Chugoku Iga		8/91		Утрроці	
						Kagak					
	10.	PCT				Pharmagene		3/00			
	11.		PCT WO97/31920			Pharmagene		9/97			_
	12.	PCT WO97/31921				harmagenesis, Inc.				↓	
	13.	PCT WO98/52933			Hoechst Mar Roussel Inc.						
	14.	PCT WO98/52951			Hoechst Mar Roussel Inc.	rion	11/98				
		OTHE	R PRIOR	ART-N	ION PATE	NT LITERATUR	RE DOCU	MENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s),						т			
	15.	Anderson <i>et al.</i> , "Synthesis, Evaluation of Chemical Reactivity, and Murine Antineoplastic Activity of 2-Hydroxy-5-(3,4-dichlorophenyl)-6,7-bis(hydroxymethyl)-2,3-dihydro-1 <i>H</i> -pyrrolizine Bis(2-propylcarbamate) and 2-Acyloxy Derivatives as Potential Water-Soluble Prodrugs <sup>1</sup> ", <i>J. Med. Chem.</i> , <u>26</u> :1333-1338 (1983).									
	16.	de Groot Franciscus M. H. et al., "Synthesis and Biological Evaluation of 2'-Carbamate-Linked and 2'-Carbonate-Linked Prodrugs of Paclitaxel: Selective Activation by the Tumor-Associated Protease Plasmin", J. Med. Chem., 43:3093-3102 (2000).									

EXAMINER	DATE CONSIDERED



Sheet

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Form PTO-1449 (Modified) (Use several sheets if necessary)

of

2

2

COMPLETE IF KNO	OWN
Application Number	10/591,358
Filing Date	August 31, 2006
First Named Inventor	Yuan et al.
Group Art Unit	1625
Confirmation No.	9546
Examiner Name	To be Assigned
Attorney Docket No.	57070-8021.US00

<ol> <li>Dittert, L.W. et al., "Acetaminophen Prodrugs I Synthesis, Physicochemical Properties, and Analgesic Activity", Journal of Pharmaceutical Sciences, 57(5):774-780 (1968).</li> <li>Dittert, L.W. et al., "Acetaminophen Prodrugs II Effect of Structure and Enzyme Source on Enzymatic and Nonenzymatic Hydrolysis of Carbonate Esters," J. of Pharm. Sciences, 57(5):780-783 (1968).</li> <li>Hansen et al., "Carbamate Ester Prodrus of Dopaminergic Compounds: Synthesis, Stability, and Bioconversion", Journal of Pharmaceutical Sciences, 80(8):793-798 (1991).</li> <li>Hansen et al., "Ketobemidone prodrugs for buccal delivery", Acta Pharm. Nord., 3(2):77-82 (1991).</li> <li>Huang et al., "Hydrobysis of Carbonates, Thiocarbonates, Carbamates, and Carboxylic Esters of α-Naphthol, β-Naphthol, and p-Nitrophenol by Human, Rat, and Mouse Liver Carboxylesterases", Pharmaceutical Research, 10(5):639-648 (1993).</li> <li>Kahns et al., "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), Pharmaceutical Research, 10(1):68-74 (1993).</li> <li>Nassar et al., "Effects of Structural Variations on the Rates of Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", Journal of Pharmaceutical Sciences, 81(3):295-298 (1992).</li> </ol>			
and Enzyme Source on Enzymatic and Nonenzymatic Hydrolysis of Carbonate Esters," <i>J. of Pharm. Sciences</i> , 57(5):780-783 (1968).  19. Hansen et al., "Carbamate Ester Prodrus of Dopaminergic Compounds: Synthesis, Stability, and Bioconversion", <i>Journal of Pharmaceutical Sciences</i> , 80(8):793-798 (1991).  20. Hansen et al., "Ketobemidone prodrugs for buccal delivery", <i>Acta Pharm. Nord.</i> , 3(2):77-82 (1991).  21. Huang et al., "Hydrolysis of Carbonates, Thiocarbonates, Carbamates, and Carboxylic Esters of α-Naphthol, β-Naphthol, and <i>p</i> -Nitrophenol by Human, Rat, and Mouse Liver Carboxylesterases", <i>Pharmaceutical Research</i> , 10(5):639-648 (1993).  22. Kahns et al., "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), <i>Pharmaceutical Research</i> , 10(1):68-74 (1993).  23. Nassar et al., "Effects of Structural Variations on the Rates of Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", <i>Journal of Pharmaceutical Sciences</i> , 81(3):295-298 (1992).	17.	Physicochemical Properties, and Analgesic Activity", Journal of	
Compounds: Synthesis, Stability, and Bioconversion", <i>Journal of Pharmaceutical Sciences</i> , 80(8):793-798 (1991).  20. Hansen et al., "Ketobemidone prodrugs for buccal delivery", <i>Acta Pharm. Nord.</i> , 3(2):77-82 (1991).  21. Huang et al., "Hydrolysis of Carbonates, Thiocarbonates, Carbamates, and Carboxylic Esters of α-Naphthol, β-Naphthol, and <i>p</i> -Nitrophenol by Human, Rat, and Mouse Liver Carboxylesterases", <i>Pharmaceutical Research</i> , 10(5):639-648 (1993).  22. Kahns et al., "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), <i>Pharmaceutical Research</i> , 10(1):68-74 (1993).  23. Nassar et al., "Effects of Structural Variations on the Rates of Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", <i>Journal of Pharmaceutical Sciences</i> , 81(3):295-298 (1992).	 18.	and Enzyme Source on Enzymatic and Nonenzymatic Hydrolysis of	
<ul> <li>Pharm. Nord., 3(2):77-82 (1991).</li> <li>21. Huang et al., "Hydrolysis of Carbonates, Thiocarbonates, Carbamates, and Carboxylic Esters of α-Naphthol, β-Naphthol, and p-Nitrophenol by Human, Rat, and Mouse Liver Carboxylesterases", Pharmaceutical Research, 10(5):639-648 (1993).</li> <li>22. Kahns et al., "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), Pharmaceutical Research, 10(1):68-74 (1993).</li> <li>23. Nassar et al., "Effects of Structural Variations on the Rates of Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", Journal of Pharmaceutical Sciences, 81(3):295-298 (1992).</li> </ul>	19.	Compounds: Synthesis, Stability, and Bioconversion", Journal of	
Carbamates, and Carboxylic Esters of α-Naphthol, β-Naphthol, and <i>p</i> -Nitrophenol by Human, Rat, and Mouse Liver Carboxylesterases", <i>Pharmaceutical Research</i> , 10(5):639-648 (1993).  22. Kahns <i>et al.</i> , "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), <i>Pharmaceutical Research</i> , 10(1):68-74 (1993).  23. Nassar <i>et al.</i> , "Effects of Structural Variations on the Rates of Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", <i>Journal of Pharmaceutical Sciences</i> , 81(3):295-298 (1992).		1	
<ul> <li>Kahns et al., "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), Pharmaceutical Research, 10(1):68-74 (1993).</li> <li>Nassar et al., "Effects of Structural Variations on the Rates of Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", Journal of Pharmaceutical Sciences, 81(3):295-298 (1992).</li> </ul>	21.	Carbamates, and Carboxylic Esters of $\alpha$ -Naphthol, $\beta$ -Naphthol, and $p$ -Nitrophenol by Human, Rat, and Mouse Liver Carboxylesterases",	
Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", <i>Journal of Pharmaceutical Sciences</i> , <u>81</u> (3):295-298 (1992).	22.	Kahns et al., "Prodrugs of Peptides. 18. Synthesis and Evaluation of Various Esters of Desmopressin (dDAVP), Pharmaceutical Research,	
	23.	Enzymatic and Nonenzymatic Hydrolysis of Carbonate and Carbamate Esters", <i>Journal of Pharmaceutical Sciences</i> , <u>81</u> (3):295-	
24. Savolainen <i>et al.</i> , "Synthesis and <i>in vitrolin vivo</i> evaluation of novel oral <i>N</i> -alkyl- and <i>N</i> , <i>N</i> -dialkyl-carbamate esters of entacapone," <i>Life Sciences</i> , 67:205-216 (2000).	24.		
Tunek <i>et al.</i> , "Hydrolysis of <sup>3</sup> H-Bambuterol, A Carbamate Prodrug of Terbutaline, in Blood from Humans and Laboratory Animals <i>In Vitro</i> ", <i>Biochemical Pharmacology</i> , <u>37</u> (20):3867-3876 (1988).	25.	Terbutaline, in Blood from Humans and Laboratory Animals In Vitro",	
26. Weibel <i>et al.</i> , "Macromolecular prodrugs IXX. Kinetics of hydrolysis of benzyl dextran carbonate ester conjugates in aqueous buffer solutions and human plasma", <i>Acta Pharm. Nord.</i> , 3(3):159-162	26.	Weibel et al., "Macromolecular prodrugs IXX. Kinetics of hydrolysis of benzyl dextran carbonate ester conjugates in aqueous buffer	
	27.	Yang et al., Tetrahedron Letters, 38(39):6865-6868 (1997).	
27. Yang et al., Tetrahedron Letters, <u>38</u> (39):6865-6868 (1997).	28.	Yu et al., Chinese Chemical Letters, 2(12):937-940 (1991).	

EXAMINER	DATE CONSIDERED
270 1011111211	SATE CONCIDENCES
	i